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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/323,765	06/01/1999	MARK D. SCOTT	259.006US1	9616

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MARK A. LITMAN
MARK A. LITMAN AND ASSOCIATES, P.A.
YORK BUSINESS CENTER, SUITE 205
3209 WEST 76TH ST.
EDINA, MN 55435

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/323,765	Applicant(s) SCOTT ET AL.	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 27,29,30 and 32-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26,28 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/04 has been entered.
2. This application contains claims 27, 29-30 & 32-52 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for no antecedent basis for the recitation of "nuclear" is withdrawn due to the amendment of the claim.
4. The rejection of claims 2-7, 9, 18-19, 23-25, 28 & 31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,908,624 is withdrawn due to the submission of a terminal disclaimer on 1/23/02.
5. Applicant's arguments filed 1/23/02 have been fully considered but they are not deemed to be persuasive.

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6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 19-23, 28 & 31 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No. 13 (mailed 4/10/01) & 16 (mailed 10/03/01), and as follows.

As previously made of record, the recitation of "said linking moieties..." has no proper antecedent basis in base claim 2 (i.e., as it relates to claims 19-23 & 28). Claim 31 also remains indefinite because a "platelet" is an "anuclear" cell, and a not "nuclear" cell, as recited in base claim 2.

8. Claims 2-7, 18-21, 23-25, 28 & 31 stand rejected under 35 U.S.C. 102(e) as being anticipated by Desai et al. (U.S. Patent 5,578,442), *in light of Lin et al. (1976)* for the reasons made of record in Paper No. 13 (mailed 4/10/01) & 16 (mailed 10/03/01), and as follows.

In contrast to Applicants' assertions, and as previously made of record, Desai clearly teach "covalent bonding" through, for example, free radical polymerization (i.e., col. 4, lines 40-54; col. 5, lines 13-26), and through UV-crosslinking (e.g., col. 3, lines 57-61). For example, Lin et al. teach that UV-crosslinking forms **covalent bonds** (e.g., page 947, 1st column). Thus, Applicants' arguments are moot; consistent with that held by the court in *Ex parte Gray*, *In re Best*, *In re Brown*, *In re Thorpe*, and *In re Marosi* previously made of record.

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9. Claims 1, 4, 8, 10-16, 24 & 26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Francis et al. (WO 95/06058), for the reasons made of record in Paper No. 13 (mailed 4/10/01) and 16 (mailed 10/03/01), and as follows.

It is noted that Applicants previously acknowledged that "Francis does apparently incidentally show the covalent bonding of a moiety (including PEG, the erythrocytes of Example 7) to the surface of a red blood cell...", but "done for... [a different] purpose", which alternatively supports the rejection made of record for these claims; consistent with that held by the courts in *Ex parte Gray*, *In re Best*, *In re Brown*, *In re Thorpe* and *In re Marosi* previously made of record. Thus, Applicants' arguments to claim limitations not recited in the claims are moot, and because whatever Francis' "intent" may have been, or not, is immaterial to whether Francis teach the currently and broadly *claimed* products. In other words, inherent properties are inherent whether they are recognized by a reference, or not.

10. Claims 1, 4, 8, 14-16, 24 & 26 stand rejected under 35 U.S.C. 102(a) as being anticipated by Jeong et al. (1996), for the reasons made of record in Paper No. 13 & 16, and as follows.

It is again noted that no "official correspondence from Marcel Dekker clearly identifying the publication date of the Jeong et al. article" has been submitted by Applicants.

11. Claims 1-26, 28 & 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al., *in light of Lin et al. (1976)*, and in view of Francis et al. (WO 95/06058), for the reasons made of record in Paper No. 13 & 16, and as follows.

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In contrast to Applicants' assertions, the instant rejection does not stand or fall solely on the teachings of Francis et al., especially in light of the further evidence provided by the Examiner; consistent with that held by the court in *In re Brown*, previously made of record.

In summary, the teachings of Desai et al., *in light of Lin et al.*, and in view of Francis et al., clearly give rise to non-immunogenic cells by virtue of the intrinsic properties of the cells made by Desai et al., in view of Francis et al., which would be non-immunogenic, by definition. In other words, Applicants' arguments do not accurately address the rejection made of record, and therefore, are not persuasive.

Thus, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to include Francis' red blood cells (RBCs), and alternate methods of covalently attaching other non-immunological polymers to cells, in Desai's non-immunological cell compositions, because of the common problems of non-compatible antigenic sites between different species/individuals for both nuclear and anuclear cells (i.e., RBCs and platelets), especially if such tissue/blood is scarce, and because Desai et al. disclose in their Detailed Description of the Invention that "[t]he process of the present invention can be used for rendering non-immunogenic *any* cell, tissue, organ, or system of organs, and the like, that may be used for transplant or the like" [emphasis added] (col. 6, lines 15-18); thereby, providing the motivation for using any cell type, including RBCs and platelets (i.e., as it relates especially to claims 15-23, 26 & 28) as a substrate for making non-immunogenic cell compositions.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.



Robert C. Hayes, Ph.D.

May 27, 2004

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